

REMARKS

In accordance with the remarks contained on pages 2 and 3 of the Office action, claims 86-89 have been cancelled.

In response to the Office action's remarks regarding the claim for priority (page 3, section 2), the claim for priority has been amended to include the final disposition of the issued parent application.

In accordance with the remarks contained on page 3, section 3 of the Office action, the Title has been amended.

Claims 37-85 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kanesaka in view of Heinonen and Haluszka (Office action, page 4, section 5). Applicants have amended claims 37, 48, and 66. Reconsideration is respectfully requested.

Claim 37 (as amended) recites, inter alia, "inputting, into the control device, **data representing only a body length of a patient** to be ventilated" and "calculating, in the control device, at least one ventilation parameter **based upon said data**" (emphasis added). Claims 48 and 66 have been similarly amended. Such features are advantageous for more accurately predicting a ventilator rate (page 9, lines 1-4).

In rejecting claims 37-85, the Office action indicates that Kanesaka substantially discloses the claimed invention including calculating ventilatory parameters based upon data that represents only body length. However, the Office action contains no indication

as to where calculating ventilatory parameters based upon data that represents only body length is disclosed within the Kanesaka reference. Applicants respectfully submit that at least this claimed feature is not disclosed by Kanesaka. Kanesaka discloses a ventilating device for supplying breathing gas to a patient. Kanesaka's device detects malfunctions such as lack of breathing gas, disconnection of the connectors, and mechanical malfunctions, and in certain cases can enable an auxiliary system having a separate gas inlet. The device must be manually set based on such parameters as patient weight, height, gender, and other clinical conditions (col. 4, lines 17-21).

The Office action further indicates that Heinonen fails to disclose the recited calculation of ventilatory parameters based upon data representing only body length.

Also, the Office action states that Haluszka includes the recited calculation of ventilatory parameters based upon data representing only body length and that it would have been obvious for one of ordinary skill in the art to combine Haluszka with Heninonen and Kanesaka to arrive at the recited invention of claims 37-85. Applicants respectfully traverse.

Applicants respectfully disagree that Haluszka is in the same field of endeavor as the recited invention. Applicants submit that the Haluszka reference is non-analogous to the field of ventilatory devices, instead being directed to measurements taken during medical examinations, an entirely separate field of endeavor. As stated in M.P.E.P. §2141.01(a), "[i]n order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of the applicant's endeavor or, if not,

then be reasonably pertinent to the particular problem with which the invention was concerned.”

The present invention is directed to a method of operating a ventilator, which includes but is not limited to “calculating at least one ventilation parameter based upon the input body length of the patient”, and using that parameter in assisting a patient in respirating. The Haluszka reference, on the other hand, is directed to the examination of children’s lungs. Haluszka states that body height was the best predictive variable for all measured parameters in examining children’s lungs (paragraph 2). However, Haluszka does not provide an explanation as to what the body height is best at predicting, nor does it provide any correlation of body height to ventilatory parameters, limits or alarms as recited in the claims. Thus, the Haluszka reference is not in applicants’ field of endeavor nor is it “reasonably pertinent to the particular problem with which the invention is concerned”. Consequently, the Haluszka reference is an improper reference to be relied upon as a basis for a rejection.

Furthermore, applicants submit that, even if Haluszka was an appropriate reference to be relied upon, there is no motivation to combine the teachings of Haluszka with Kanesaka and Heinonen. Specifically, as noted above, while Haluszka states that body height was, in the study performed, “the best predictive variable”, Haluszka nowhere states what body height is the best at predicting. There is no teaching in the Haluszka reference that body height alone can be used to predict appropriate ventilation parameters for a person. Hence, Haluszka fails to add anything pertinent to the disclosures of Kanesaka and

Heinonen, and one ordinarily skilled in the art would not have been motivated to combine Haluszka with the other cited references.

Additionally, applicants submit that even if one of ordinary skill in the art was to have combined the teachings of Haluszka with the other cited references, the combination would still not result in the recited invention since none of the cited references teach or suggest a method of operating a ventilator that includes inputting data representing only a body length and calculating at least one ventilation parameter based upon that input data.

The Office action also states that the current claim language is “open and does not include a negative limitation that exclusively limits the data input to only patient height” (page 5, paragraph 2). In response, claims 37, 48, and 66 have been amended to clarify that the calculating step is based on the recited data, which represents only body length. For at least the above reasons, the rejection of claims 37, 48, 66, and all claims dependent therefrom should be withdrawn.

Claims 37-85 also stand rejected as being unpatentable over claims 1-4 of U.S. Patent No. 6,000,396 (Office Action, page 7, section 7) under the judicially created doctrine of obviousness-type double patenting. Applicants herewith submit a Terminal Disclaimer executed by an officer of the University of Florida Research Foundation, Inc. (“UFRF”). The UFRF is the owner of the present application and U.S. Patent No. 6,000,396 by way of assignment recorded at Reel 13200, Frame 0868 (copy enclosed).

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

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Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

The title has been replaced as follows:

[HYBRID MICROPROCESSOR CONTROLLED VENTILATOR UNIT]
VENTILATORY METHOD UTILIZING BODY LENGTH-BASED PARAMETER
CALCULATIONS

Paragraph at line 1 of page 1 has been replaced as follows:

This application is a continuation of application Ser. No. 08/516,478, filed on August 17, 1995, now U.S. Patent No. [_____] 6,000,396, issued on December 14, 1999, which is hereby incorporated by reference in its entirety.

Claims 37, 48, and 66 have been rewritten:

37. (Amended) A method of operating a ventilator, comprising the steps of:

providing a ventilator having a control device, the control device including means for inputting data;

inputting, into the control device, data representing only a body length of a patient to be ventilated;

calculating, in the control device, at least one ventilation parameter[, wherein said calculating step consists essentially of calculating the at least one ventilation parameter] based upon [the input body length of the patient] said data; and providing ventilation in accordance with the calculated at least one ventilation parameter.

48. (Amended) A method of operating a ventilator, comprising the steps of:

providing a ventilator having a control device, the control device including means for inputting data;

inputting, into the control device, data representing only a body length of a patient to be ventilated;

calculating, in the control device, at least one ventilatory limit[, wherein said calculating step consists essentially of calculating the at least one ventilatory limit] based upon [the input body length of the patient] said data; and

limiting at least one ventilation parameter in accordance with the calculated at least one ventilatory limit.

66. (Amended) A method of operating a ventilator, comprising the steps of:

providing a ventilator having a control device, the control device including means for inputting data;

inputting, into the control device, data representing only a body length of a patient to be ventilated;

calculating, in the control device, at least one ventilation alarm setting[, wherein said calculating step consists essentially of calculating the at least one ventilation alarm setting] based upon [the input body length of the patient] said data; and

setting at least one ventilation alarm in accordance with said at least one ventilation alarm setting.

Claims 86-89 have been canceled.